

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF TENNESSEE  
AT KNOXVILLE**

UNITED STATES OF AMERICA and	)	
STATE OF TENNESSEE,	)	
	)	
Plaintiffs,	)	Civil Action No.
	)	
v.	)	
	)	
WALGREEN COMPANY,	)	
	)	
Defendant.	)	

**COMPLAINT OF THE UNITED STATES OF AMERICA  
AND THE STATE OF TENNESSEE**

1. This civil action is brought in the name of the United States of America and the State of Tennessee (collectively the Plaintiffs), by and through Francis M. Hamilton III, Acting United States Attorney for the Eastern District of Tennessee, and Herbert H. Slatery III, Attorney General and Reporter for the State of Tennessee (State), against Defendant Walgreen Company (Defendant) pursuant to the False Claims Act (FCA), 31 U.S.C. §§ 3729, *et seq.*, and the Tennessee Medicaid False Claims Act (TMFCA), Tenn. Code Ann. §§ 71-5-181, *et seq.*, and common law theories of payment by mistake and unjust enrichment.

2. This action arises from Defendant's submission, or having caused the submission, of false or fraudulent claims for payment to the Tennessee State Medicaid Program (TennCare) for prescription medications. This action also arises from Defendant's use of false statements, or having caused the submission of false statements, to TennCare insofar as Defendant knew or should have known that the patients' prior authorization forms and medical records falsely characterized the medical condition of patients in order to obtain TennCare payments that Defendant would not otherwise have received. Finally, this action arises from Defendant's failure

to return the TennCare payments that it improperly received, even after Defendant was made aware that it had billed TennCare and received payment for prescription medications dispensed to individuals who did not meet the clinical criteria for TennCare coverage.

3. Defendant operates a specialty pharmacy located in the Holston Valley Medical Center at 130 West Ravine Road in Kingsport, Tennessee (Walgreens #13980, hereafter referred to as the Kingsport Pharmacy), through which these prescription medications were provided.

4. Beginning in October 2014 through December 2016, the United States and the State suffered millions of dollars in damages when TennCare paid Defendant for false or fraudulent claims for prescriptions filled at the Kingsport Pharmacy. Defendant was unjustly enriched as a result of the fraudulent scheme, and its knowing retention of those monetary benefits is inequitable under these circumstances.

#### **Jurisdiction and Venue**

5. This Court has jurisdiction under 31 U.S.C. § 3732(a) and (b), and 28 U.S.C. §§ 1331 and 1345, and 1367(a).

6. This Court may exercise personal jurisdiction over Defendant under 31 U.S.C. §3732(a) because Defendant transacts business in this District, and because Defendant submitted claims for payment to the United States and the State of Tennessee for prescriptions filled in this District and it received payments from the United States and the State of Tennessee for those prescriptions.

7. Venue is proper in this District under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Defendant transacts business in this District and the events giving rise to the causes of action in this complaint occurred in this District.

## **Parties**

8. Plaintiff United States brings this action on behalf of the Department of Health and Human Services (HHS), which includes the Centers for Medicare and Medicaid Services (CMS).

9. Plaintiff State of Tennessee brings this action on behalf of its Medicaid program known as TennCare.

10. Defendant Walgreen Company is an Illinois corporation with its headquarters in Deerfield, Illinois. Defendant owns a national chain of pharmacies commonly known as Walgreens. During all times relevant to this Complaint, Defendant owned and operated the Kingsport Pharmacy and provided pharmacy services to TennCare enrollees.

## **The Federal False Claims Act**

11. The FCA provides, in pertinent part, that a person who:

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [. . .] or

(G) . . . knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable to the United States Government [for statutory damages and such penalties as are allowed by law].

31 U.S.C. §§ 3729(a)(1)(A)-(B), (G) (2010).

12. The FCA further provides:

the terms “knowing” and “knowingly” –

(A) mean that a person, with respect to information –

(i) has actual knowledge of the information;

- (ii) acts in deliberate ignorance of the truth or falsity of the information; or
- (iii) acts in reckless disregard of the truth or falsity of the information, and

(B) require no proof of specific intent to defraud[.]

31 U.S.C. § 3729(b)(1).

13. The FCA provides that a person is liable to the United States Government for three times the amount of damages that the Government sustains because of the act of that person, plus a civil penalty of (a) \$5,500 to \$11,000 per violation occurring between 1999 and July 31, 2016; and (b) \$10,781 to \$21,563 per violation occurring between August 1, 2016 and February 3, 2017.

31 U.S.C. § 3729(a)(1); 28 C.F.R. §§ 85.3 & 85.5.

#### **The Tennessee Medicaid False Claims Act**

14. The TMFCA provides, in pertinent part, that a person who:

(A) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval under the medicaid program;

(B) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim under the medicaid program; [. . .]  
or

(D) Knowingly and improperly avoids, or decreases an obligation to pay or transmit money or property to the state, relative to the medicaid program;

is liable to the state for [statutory damages and such penalties as are allowed by law].

Tenn. Code Ann. § 71-5-182(a)(1)(A)-(B), (D).

15. The TMFCA defines “knowing” and “knowingly” to mean that a person, with respect to information:

- (1) Has actual knowledge of the information;

- (2) Acts in deliberate ignorance of the truth or falsity of the information; or
- (3) Acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

Tenn. Code Ann. § 71-5-182(b).

16. The TMFCA provides that a person is liable to the State for three times the amount of damages that the State sustains because of the act of that person, plus a civil penalty of not less than \$5,000 and not more than \$25,000. Tenn. Code Ann. § 71-5-182(a)(1).

### **The TennCare/Medicaid Program**

17. The federal Medicaid program was enacted under Title XIX of the Social Security Act of 1965, 42 U.S.C. §§ 1396 to 1396w-5, and provides funding for medical and health-related services for certain individuals and families with low incomes and limited or no financial resources.

18. The Medicaid program is administered as a joint federal-state program. 42 U.S.C. § 1396b. If a state elects to participate in the program, the costs of Medicaid are shared between that state and the federal government. 42 U.S.C. § 1396a(a)(2). In order to receive federal funding, a participating state must comply with requirements imposed by the Social Security Act and regulations promulgated thereunder.

19. The State of Tennessee participates in the Medicaid program pursuant to Tenn. Code Ann. §§ 71-5-101 to -199. The federal government, through CMS, provides approximately 65% of the funds used by TennCare to provide medical assistance to persons enrolled in the Medicaid program, with the balance of the funds coming from the State of Tennessee.

20. In return for the receipt of federal funds, the State of Tennessee is required to administer TennCare in conformity with a state plan that satisfies the requirements of the Social Security Act and accompanying regulations. 42 U.S.C. §§ 1396-1396w-5; Tenn. Code Ann. § 71-5-102. TennCare operates as a special demonstration project authorized by the Secretary of the

United States Department of Health and Human Services under the waiver authority conferred by 42 U.S.C. § 1315. The Tennessee Department of Finance and Administration supervises TennCare's administration of medical assistance for eligible recipients. Tenn. Code Ann. § 71-5-124. The Department of Finance and Administration is authorized to promulgate rules and regulations to effectuate the purposes of TennCare. Tenn. Code Ann. § 71-5-134.

21. At all times relevant to the allegations in this Complaint, TennCare contracted with Magellan Medicaid Administration (Magellan), to oversee the financial, clinical and managerial aspects of the TennCare pharmacy program as the Pharmacy Benefits Manager (PBM).

22. Magellan's duties included the processing and payment of claims for reimbursement for pharmacy services. TennCare Rule 1200-13-13-.04(1)(b)(25).

23. In turn, Defendant contracted with Magellan to provide prescription filling activities under the TennCare program. *See* Walgreen Participating Pharmacy Agreement, attached as Exhibit A.

### **TennCare Reimbursement Requirements**

24. Under Tennessee law, "TennCare is authorized to implement, either independently or in combination with a state preferred drug list (PDL), . . . prior authorization and step therapy requirements." Tenn. Code Ann. § 71-5-197(b).

25. TennCare requires providers of pharmacy services – including Defendant – to comply with the clinical criteria for the TennCare PDL and with the TennCare Pharmacy Manual. Exhibit A, at ¶ 2.2.

26. The PDL is reviewed by the TennCare Pharmacy Advisory Committee. It contains a list of covered prescription drugs, listed by therapeutic category and by preferred or non-preferred status. The PDL is required to be updated at least quarterly. *Id.* at ¶ 1.19.

27. For each prescription medication, the PDL lists the requirements that must be met

for the cost of the drug to be covered by TennCare. Some prescription drugs also require prior authorization before they are covered by TennCare, and for such drugs the PDL contains links to prior authorization forms and applicable clinical criteria.

28. In order to be reimbursed for a claim for a drug that requires prior authorization per the PDL, the pharmacy services provider must ensure that the prior authorization requirements are met. *Id.* at ¶ 3.2.

29. TennCare, through its PBM, will not pay benefits for claims submitted without prior authorization where one is required or where prior authorization has been denied.

30. At all relevant times, TennCare through its PBM Magellan routinely denied payment to pharmacy providers who submitted a claim for a prescription on the PDL when the prescriber had not obtained a required prior authorization.

### **TennCare Coverage for Hepatitis C Medications**

31. Hepatitis C is a viral infection that attacks the liver and causes degrees of fibrosis that vary among the infected populations. It is spread by contact with contaminated blood, for example, from sharing needles or from unsterile tattoo equipment. Most people have no symptoms. Those who do develop symptoms may have fatigue, nausea, loss of appetite, and the yellowing of the eyes and skin.

32. At all relevant times, certain medications that were available for treatment of Hepatitis C from 2014 to 2016 required prior authorization by the PBM Magellan before such medications could be provided to TennCare enrollees. These medications are commonly known as direct acting antivirals (DAAs), and they include Viekira Pak® (National Drug Code [NDC] 00074-3093-28), Harvoni® (NDC 61958-1801-01), Sovaldi® (NDC 61958-1501-01), and

Daklinza® (NDC 0003-0215-01). At all relevant times, these drugs cost anywhere from \$60,000 to more than \$90,000 for one 12-week course per Hepatitis C patient.

33. At all relevant times, the clinical criteria for the PDL (“PDL criteria”) required that a patient’s medical condition meet certain clinical metrics in order to receive a prior authorization for one of these four prescription drugs. One requirement was that a patient must have a certain level of disease severity based on the amount of fibrosis of the liver. The patient’s fibrosis level could be measured by one of four scoring systems for chronic liver disease:

- (i) Metavir score;
- (ii) Fibrotest (FibroSure) score;
- (iii) Ultrasound based on transient elastography (Fibroscan) score; or
- (iv) Fibrosis-4 index (FIB-4).

34. Metavir scores are reported on laboratory results derived from a liver biopsy and use the values F0 through F4 to note the patient’s fibrosis stage. F0 is the Metavir score that corresponds to the least amount of fibrosis of the liver, indicating no fibrosis. A Metavir score of F4 equates to cirrhosis.

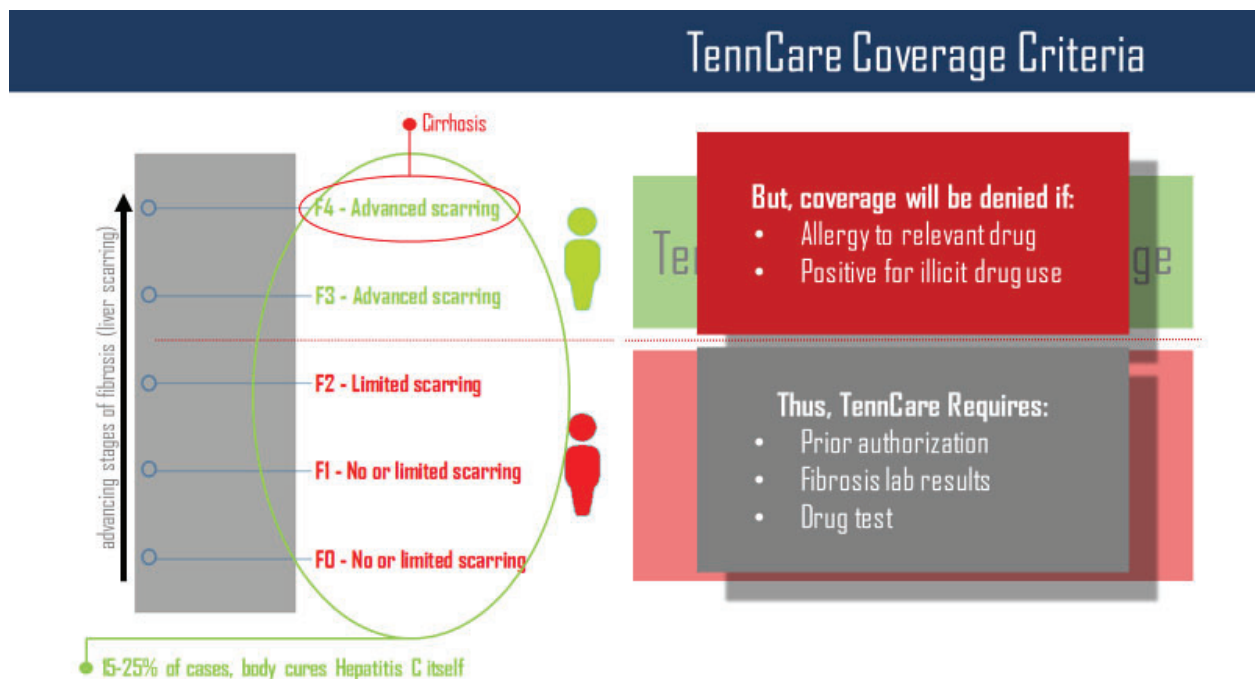
35. Fibrotest/Fibrosure scores can be derived from a blood test or radiologic test, and are reported in laboratory results as a decimal figure between 0.00 and 1.00. Fibrotest/Fibrosure scores can also be correlated to fibrosis stages F0 to F4.

36. At all relevant times, for prior authorization requests made based on a patient’s disease severity, the PDL criteria for Viekira Pak®, Harvoni®, Sovaldi®, and Daklinza® required that a patient have at least one of the following in order for TennCare to pay for these prescription medications:

- (i) Metavir score of at least F3 (advanced fibrosis); or
- (ii) Fibrotest (FibroSure) score of  $\geq 0.59$ ; or

- (iii) Ultrasound based on transient elastography (Fibroscan) score of  $\geq 9.5$  kPa; or
- (iv) Fibrosis-4 index (FIB-4)  $> 3.25$ .

37. At all relevant times, the PDL criteria for these four prescription medications also required confirmation that the patient was not “actively participating in illicit substance abuse or alcohol abuse,” and that if the patient had “a prior history of substance or alcohol abuse, then patient has been free of substance and alcohol abuse for previous 6 months.” This requirement included submission of supporting documentation such as a recent drug screen.



38. The process to seek prior authorization for these medications in order to receive reimbursement by TennCare is, and was at all relevant times, as follows:

- a. The prescriber determines that a medication on the PDL is necessary to treat a patient's condition.
- b. The prescriber answers a series of questions about the patient by checking “yes” or “no” on the prior authorization form for that particular medication.

- c. The prescriber signs the prior authorization form and submits the form to Magellan, the TennCare PBM, along with the patient's supporting medical records.
- d. The PBM evaluates the prior authorization form and supporting medical records to determine if the patient satisfies the coverage eligibility requirements for the prescribed medication.
- e. If the PBM approves the prior authorization request, the pharmacy may then dispense the medication and file a claim for reimbursement.
- f. TennCare then reimburses the pharmacy for the prescribed medication cost through the PBM.

### **The False Claims Conduct**

39. Defendant Walgreen employed Amber Reilly in its Specialty Pharmacy located in the Holston Valley Medical Center in Kingsport, Tennessee.

40. Ms. Reilly began working for Defendant on or about September 5, 2009 as a pharmacy intern, then as a pharmacist, and was later promoted to the position of "Registered Store Manager, On Site Pharmacy" for the Kingsport Pharmacy on or about March 2, 2013. As the Registered Store Manager of the Kingsport Pharmacy, Ms. Reilly was a salaried employee of Defendant and was evaluated on a number of factors, including increasing profitable pharmacy sales and her ability to "build more relationships with prescribers/health care professionals to increase pharmacy sales[. . .]."

41. In her capacity as Registered Store Manager, Ms. Reilly began visiting physician offices in the region to promote Defendant's pharmacy services and persuade physicians to refer patients with Hepatitis C to Defendant's Kingsport Pharmacy. These sales visits to local physicians were referred to as "Details" in Defendant's corporate culture.

42. During at least one visit, Ms. Reilly stated to providers that she had success in getting prior authorizations for Hepatitis C medications approved when other pharmacies could not. Other pharmacies could not get approval because many of the patients did not meet the PDL criteria.

43. Based on Ms. Reilly's representations that Defendant's Kingsport Pharmacy could obtain approvals for TennCare enrollees with Hepatitis C when other pharmacies could not, physicians and other healthcare providers began sending prescriptions for these TennCare enrollees to Defendant's Kingsport Pharmacy, along with prior authorization forms and supporting laboratory reports and medical records.

44. Upon receiving these medical records and prior authorization forms at the Kingsport Pharmacy, Ms. Reilly, acting in her capacity as Defendant's pharmacist and Registered Store Manager and to the financial benefit of Defendant, fraudulently and materially falsified, altered, or recreated the TennCare enrollees' prior authorization forms, medical records, and/or drug test results in order to indicate that the patient was eligible to receive TennCare coverage pursuant to the PDL criteria.

45. Ms. Reilly also directed at least one other employee of Defendant to falsify, alter, or recreate TennCare enrollee's prior authorization forms, medical records, and/or drug test results in order to indicate that the patient was eligible to receive TennCare coverage pursuant to the PDL criteria.

46. Ms. Reilly's conduct took place from October 2014 through June 2016. Defendant, through Reilly, knowingly submitted, and caused to be submitted, materially false information to TennCare for a total of 65 TennCare enrollees who did not meet the PDL criteria for reimbursement. The 65 enrollees consist of enrollees whose initial prior authorization request was denied for failure to meet one or more clinical criteria and other enrollees who did not otherwise

meet the clinical criteria for coverage and would have been denied had Ms. Reilly not submitted a falsified prior authorization request and medical records on their behalf. As a result of the submission of false information by Defendant, Magellan authorized Defendant to fill Hepatitis C prescriptions for these 65 TennCare enrollees and paid millions of dollars to Defendant.

47. Ms. Reilly first began to falsify medical records in order to fraudulently obtain prior authorization after an encounter with a patient whose prior authorization request had been denied. In that instance, the prior authorization was filed by the patient's physician. The PBM denied coverage for failure to meet clinical requirements. Ms. Reilly then altered the medical records, falsified the relevant criteria, and refiled the prior authorization, which was subsequently approved.

48. Defendant submitted materially false medical lab reports for nearly all of the 65 TennCare enrollees. Ms. Reilly, acting in her capacity as Defendant's Registered Store Manager and to the financial benefit of Defendant, altered—and/or directed another employee to alter—the Metavir score of at least 55 TennCare enrollees who had an actual score below F3. The Metavir scores for these enrollees were changed to F3 or F4.

49. Ms. Reilly, acting in her capacity as Defendant's Registered Store Manager and to the financial benefit of Defendant, altered—and/or directed another employee to alter—the Fibrotest/Fibrosure score of at least 52 TennCare enrollees who had an actual score below 0.59. The Fibrotest/Fibrosure scores for these enrollees were charged to 0.59 or above.

50. Ms. Reilly, acting in her capacity as Defendant's Registered Store Manager and to the financial benefit of Defendant, altered—and/or directed another employee to alter—both the Metavir score and the Fibrotest/Fibrosure score for 48 of 65 patients.

51. Additionally, Defendant submitted false drug lab results for at least 12 TennCare enrollees. Defendant's store manager altered—and/or directed another employee to alter—the

drug test for substance or alcohol abuse to falsely report that the patient had tested negative when the actual drug screen reported that the patient had tested positive.

52. Defendant also submitted materially false information for at least seven TennCare enrollees to obtain approval specifically for Harvoni®, the most expensive of the four prescription medications. In these cases, Ms. Reilly, acting in her capacity as Defendant's Registered Store Manager and to the financial benefit of Defendant, falsely stated on the Harvoni prior authorization form that other less expensive drugs had been tried by the patient and failed to treat the patient's infection.

53. After altering the prior authorization forms, Ms. Reilly or someone acting at the direction of Ms. Reilly, would sign the provider's name without the provider's knowledge or consent and submit the form to Magellan. Had Magellan known that the prior authorization was falsified by the pharmacy services provider, that the pharmacy services provider falsified one or more clinical criteria for eligibility, and that the prescriber did not approve the falsified prior authorization request, Magellan would not have approved the prior authorization.

54. But for Ms. Reilly's material misrepresentations that these 65 TennCare enrollees satisfied the PDL criteria, TennCare would not have paid millions of dollars to Defendant for the Hepatitis C prescription medications.

*Patient A<sup>1</sup>*

55. By way of example, Defendant—in one such instance—altered the Fibrotest/Fibrosure score on a prior authorization form for Patient A after an initial prior authorization request was denied TennCare coverage for a Sovaldi® prescription. Defendant falsified Patient A's Fibrotest score and Metavir score, altered Patient A's prior authorization form

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<sup>1</sup> Patient identities will be provided to Defendant under separate cover.

to falsely indicate clinical qualification, and forged Patient A's prescriber's signature on the records submitted for appeal.

56. Patient A's original prior authorization request was dated December 15, 2015. The form consists of both biographical information (such as name and date of birth), health and medication history, and clinical eligibility criteria for the Hepatitis C drug. Question 20 in particular seeks information on clinical criteria and asks the prescriber to "check" yes or no whether "the patient has any of" of four liver damage indicators. The prescriber can check whether the patient has "Liver biopsy showing Metavir score of F3/F4"; "Fibrotest (FibroSure) score of  $\geq 0.59$ "; "Ultrasound based transient elastography (Fibroscan) score  $\geq 9.5$  kPa"; and "Fibrosis-4 Index (FIB-4)  $> 3.25$ ." On the original prior authorization request that the prescriber submitted for Patient A, Question 20 was left unchecked, and none of the four listed conditions were checked. That was an omission that indicated that Patient A did not meet the clinical criteria for eligibility based on disease severity.

20. Please check if the patient has any of the following. If yes, documentation must be attached.

☐ Liver biopsy showing Metavir score of F3/F4

☐ Fibrotest (FibroSure) score of  $\geq 0.59$

☐ Ultrasound based transient elastography (Fibroscan) score  $\geq 9.5$  kPa

☐ Fibrosis-4 Index (FIB-4)  $> 3.25$

☐ Yes

☐ No

57. Question 26 also seeks information regarding clinical eligibility criteria. It simply asks, "Does the patient have cirrhosis?" The prescriber checked "No."

26. Does the patient have cirrhosis?

☐ Yes

☒ No

58. Patient A's original prior authorization request form included a lab report from Quest Diagnostic. The report indicated that Patient A received a Liver Fibrosis,

Fibrotest/Fibrosure score of 0.25, which classified Patient A with a Fibrosis score of F0-F1. A minimum Fibrotest/Fibrosure score of 0.59 or a Fibrosis score of F3 is a clinical requirement for eligibility.

59. Based on Patient A's scores, the patient's healthcare provider advised Patient A that he "will pprobably [*sic*] be denied due to fibrosis score (F0-F1)." But the provider nevertheless signed a prior authorization request that accurately stated Patient A's clinical status under the eligibility criteria for Sovaldi®.

60. On December 18, 2015, Magellan issued a Notice of Prior Authorization Determination denying Patient A's request for coverage of Sovaldi®, explaining that "The patient does not meet the criteria for approval of this medication. . . . Please note TennCare Criteria requires Fibrosis Stage of F3 or F4."

61. On or about December 22, 2015, Patient A's healthcare provider spoke with Defendant regarding obtaining a Sovaldi® prescription for Patient A. An entry was made in Patient A's medical records stating, ". . . Walgreens called and stated insurance needs more information to approve the Sovaldi. She said she would take care of it as long as we faxed labs to her."

62. Ms. Reilly received Patient A's prior authorization records from the provider. Ms. Reilly subsequently altered the prior authorization form, falsified the Quest Diagnostic lab report, forged the provider's signature, and submitted the falsified documents to Magellan.

63. On a second prior authorization form that is dated December 29, 2015, Ms. Reilly checked "Yes" on Question 20 (whereas the original was left unchecked) and also falsely checked that Patient A had a "Fibrotest (FibroSure) score of  $\geq 0.59$ ." On Question 26 (where the provider originally checked "No" to indicate that the patient did not have cirrhosis), Ms. Reilly falsely checked "Yes" that Patient A did in fact have cirrhosis.

20. Please check if the patient has any of the following. If yes, documentation must be attached.

☐ Liver biopsy showing Metavir score of F3/F4

☒ Fibrotest (FibroSure) score of  $\geq 0.59$

☐ Ultrasound based transient elastography (Fibroscan) score  $\geq 9.5$  kPa

☐ Fibrosis-4 index (FIB-4)  $> 3.25$

☒ Yes

☐ No

26. Does the patient have cirrhosis?

☒ Yes

☐ No

64. Ms. Reilly then signed the provider's name to the falsified second prior authorization request without the provider's knowledge or consent to the falsification, while creating the false impression that the request reflected the clinical assessment and judgment of the provider. Reilly then submitted, or caused to be submitted, the second prior authorization request to Magellan, along with supporting lab reports that were falsified to represent that Patient A's had a NASH fibrosis score of 0.78, and a NASH fibrosis stage of F4.

65. Based on the fraudulently altered documents, Patient A was approved for Sovaldi®, and TennCare paid Defendant a total of \$84,663 for the prescription medication cost.

#### ***Patient B***

66. As another example, the original lab reports for Patient B indicated she had a NASH Fibrosis Score of .04, which corresponds to a fibrosis stage of F0. Based on this score, Patient B did not meet the clinical criteria for benefits coverage for Harvoni®.

NASH - Fibrosis Stage	Comment
	F0 - No fibrosis

67. However, Ms. Reilly, acting in her capacity as pharmacist and Registered Store Manager, altered lab reports for Patient B to show that Patient B had a NASH Fibrosis Score of 0.58, and a fibrosis stage of F3. Reilly then completed and submitted a prior authorization form to TennCare's PBM, Magellan, representing that Patient B had fibrosis in the liver corresponding to a Metavir fibrosis score of at least 3. The prior authorization for Patient B was subsequently

approved, and Defendant received payments totaling \$60,474 from TennCare for her prescription medication.

Test name	Result	Flag	Units	Ref Intvl
NASH - Fibrosis Score	0.58			
NASH - Fibrosis Stage	Comment			
	Stage F3 - Bridging fibrosis with many septa			
NASH - Steatosis Score	0.47	H		0.00-0.30

### *Patient C*

68. In yet another example, Ms. Reilly submitted a second prior authorization form with forged signature, fabricated explanation, and altered medical records and lab results to qualify Patient C for coverage. In this instance, the original liver biopsy report for Patient C, submitted with a prior authorization form dated December 22, 2015, indicated that the Patient had a liver fibrosis stage between 2 and 3.

### **Surgical Pathology Report**

#### **Comment**

Mild chronic portal hepatitis with lymphoid aggregate formation (grade 1-2) and fibrosis are compatible with the clinical history of hepatitis C. In addition, there is moderate steatosis with changes consistent with superimposed steatohepatitis. The fibrosis present consists predominantly of portal and periportal fibrosis, but areas of early bridging fibrosis cannot be completely excluded (stage 2-3).

Magellan denied the December 22, 2015 prior authorization request for failure to meet clinical criteria. A Metavir fibrosis score of F3 or F4 was required to qualify for coverage.

69. Subsequently, on or about April 5, 2016, a new prior authorization form was submitted for Patient C. Defendant's store manager, however, altered the accompanying liver biopsy report to make the fibrosis level appear as F3, which would be qualifying.

#### **Comment**

Mild chronic portal hepatitis with lymphoid aggregate formation (grade 1-2) and fibrosis are compatible with the clinical history of hepatitis C. In addition, there is moderate steatosis with changes consistent with superimposed steatohepatitis. The fibrosis present consists predominantly of portal and periportal fibrosis, but areas of early bridging fibrosis cannot be completely excluded (stage F3).

70. On or about April 7, 2016, Magellan issued a Notice of Prior Authorization Determination denying Patient C's request for prior authorization because he "does not meet the criteria for approval of this medication." The Notice further explained that Patient C's "Original unaltered Liver biopsy lab result from Highlands Pathology Consultants" placed Patient C in "stage 2-3."

71. Defendant's store manager then responded to Magellan's denial by returning the Notice of Prior Authorization, via fax, with a hand-written note stating: "Attached is patient's New fibrosis score that was done on 3/23/16." With this fax, Defendant's store manager submitted a falsified lab report showing Patient C's fibrosis score as 0.69, which also corresponded with the falsified fibrosis stage of F3.

Prior Authorization Status:	Prior Authorization Begin Date:
Date of Review: 04/07/2016	Prior Authorization End Date:

The patient does not meet the criteria for approval of this medication. The request has been denied to allow pursuit of the appeal process. The patient will receive an official denial letter, complete with instructions regarding the appeal process, if applicable.

Original unaltered Liver biopsy lab result from Highlands Pathology Consultants, P.C, collected date 12/22/2014  
faxed submitted 12/22/2015 documents stage 2-3.

Attached is patient's New fibrosis  
Score that was done on 3/23/16.

Fibro Test Score	Metavir Score
0.00-0.21	F0
0.22-0.27	F0-F1
0.28-0.31	F1
0.32-0.48	F1-F2
0.49-0.58	F2
0.59-0.72	F3
0.73-0.74	F3-F4
0.75-1.00	F4

Fibrosis Score	0.69
Fibrosis Stage	F3
Footnote	SEE NOTE

That information was false because Patient C did not undergo a new test.

72. Based on the false statements made and false information provided by Defendant, Patient C's new request for prior authorization was subsequently approved.

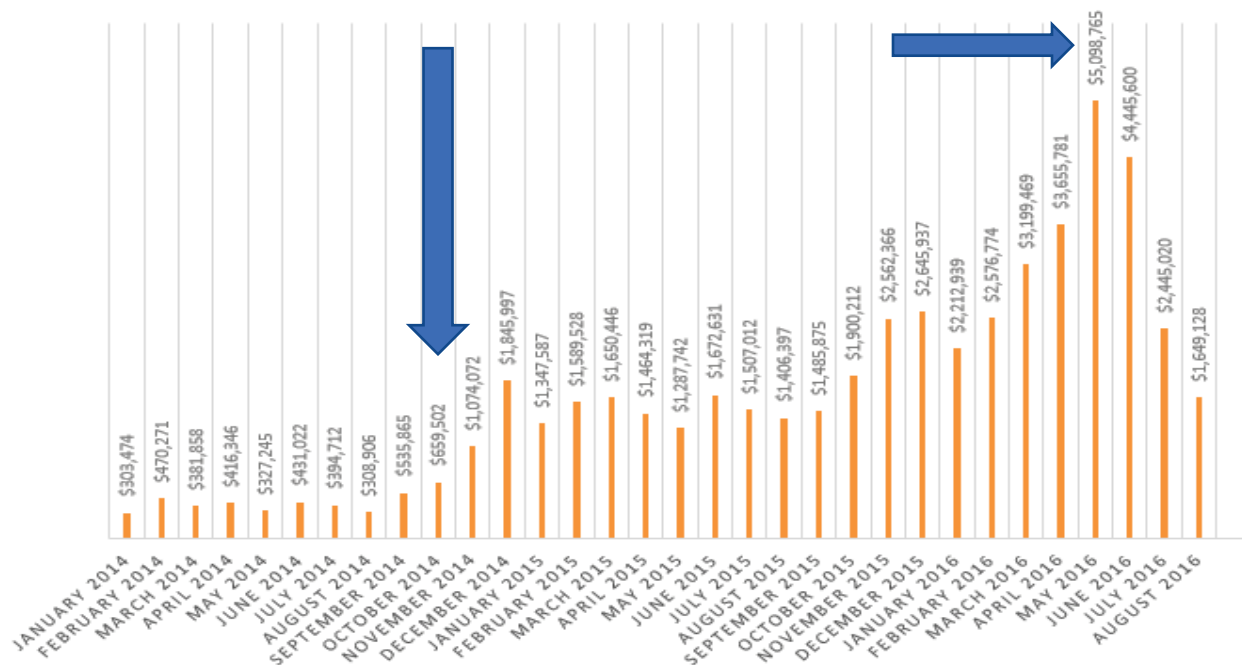
73. Later, on a third prior authorization form submitted for continuation of therapy for Patient C, Ms. Reilly hand wrote, "Attached is correct HCV RNA Level. Lab made mistake and had to re-do pat's RNA level." This, too, was false. Then she signed the patient's provider's name to the form without the provider's knowledge or consent.

Health Care Finance & Administration TennCare  
Prior Authorization Form  
Viekira®  
Access this PA form at <https://tenncare.magnanavigator.com/static/docs/prior-authorization-forms/TennCare-Viekira-PA-Request-Form.pdf>  
Please note any other information pertinent to this PA request: MD is a TN Medicaid Provider. Attached is correct HCV RNA Level. Lab made mistake and had to re-do pt's RNA level.  
Please Note: If approved, compliance with therapy is required. Authorizations may be terminated for patients who are noncompliant with therapy.  
Prescriber Signature (Required) 5/31/16 Date  
(By signature, the Physician confirms the above information is accurate and verifiable by patient records.)

74. Based on the false statements made and false information provided by Defendant, Patient C's prior authorization for continued therapy was approved. Defendant received payments from TennCare totaling \$79,977 for Patient C's prescription medication.

#### **Defendant Profited from the False Claims Submitted**

75. During the applicable time period, the Kingsport Pharmacy's revenue for October 2014, when the first false prior authorization and medical records were submitted, was \$659,502. Hepatitis C drugs accounted for 78% of the revenue for that month. In May 2016, Defendant's Kingsport Pharmacy earned \$5,098,765—an increase of 673% in less than two years.



76. This staggering revenue increase resulted from dramatic increases in revenues from payments by TennCare and other payors for Hepatitis C medications.

77. The Kingsport Pharmacy generated revenue of \$40,843,351 between October 2014 and May 2016 from all sources. All Hepatitis C drugs accounted for approximately 92% of Defendant's total revenue during that time period, while the four drugs at issue here – Daklinza®, Harvoni®, Sovaldi®, and Viekira Pak® – accounted for 77% of Defendant's total. Of the over \$30 million in payments for four drugs by Medicaid, Medicare, and private insurance payors, TennCare paid more than \$8 million. Approximately \$5.93 million of that was paid based on fraudulent prior authorization and medical records that Defendant submitted.

78. Defendant, through or at the direction of Reilly, altered patients' records and submitted false documents and claims to TennCare, to Defendant's financial benefit. In her performance review for the period September 1, 2014 through August 31, 2015 with her manager, Charles Wykes, Ms. Reilly stated, "I know what each payor requires for approval, [ . . . ] and I've become [*sic*] an expert in customizing appeal letters based on a plan's criteria. This knowledge

has been crucial in receiving approvals, which in return, has increased profits and strengthened relationships with providers.” Her manager commented “she has not only created loyal customers, but has created very loyal Dr offices and case managers and has developed our site to have a reputation of one that will go the extra mile. She [. . .] must present in a way that gains trust because I have witnessed her detail one day and the next gain several referrals from the office.”

79. At all times relevant, Defendant paid Reilly a base salary of approximately \$136,000, and an annual bonus of up to \$25,000.

80. Beginning in October 2014 through 2016, Defendant, through Reilly, knowingly presented, or caused to be presented, false claims for reimbursement to the TennCare program. Specifically, Defendant knowingly created falsified records for use in submitting claims for payment to the TennCare program. Defendant then submitted, or caused to be submitted, these false records for 65 TennCare enrollees to obtain an authorization for payment for prescription drugs on the PDL. As a result of the creation and submission of the false documents, TennCare approved prior authorization requests submitted by Defendant and paid Defendant more than \$5.9 million for these medications.

81. Defendant became aware of Ms. Reilly’s fraud as early as June 2016 and was on notice that it had received payments based on false statements and documents submitted and that it has an obligation to reimburse TennCare for such overpayments.

82. On or about June 8, 2016 and June 14, 2016, the Tennessee Bureau of Investigation served Defendant with subpoenas seeking records related to prescriptions filled for certain patients and claims and records submitted to TennCare for those patients.

83. On June 15, 2016, Defendant’s loss prevention personnel went to the Kingsport Pharmacy to investigate and recovered records that had been altered. The loss prevention personnel also spoke to an employee of Defendant who worked at the direction of Ms. Reilly, and the

employee admitted to falsifying several prior authorization records at the direction of Ms. Reilly. This discovery further put Walgreen on notice that it had obtained payments fraudulently and that it had an obligation to reimburse TennCare for such overpayments.

84. In October 2016, Ms. Reilly pleaded guilty to one count of healthcare fraud relating to at least 51 Hepatitis C patients that failed to meet TennCare eligibility requirements. Specifically, Ms. Reilly admitted that, in her role as a clinical pharmacy manager, she falsified (and directed at least one other employee to falsify) prior authorizations, medical lab reports, and drug test results so that otherwise unqualified Hepatitis C patients would satisfy TennCare's payment eligibility criteria. *See* Amber Reilly Plea Agreement, attached as Exhibit B. Accordingly, Defendant was on notice by October 2016 that it had received payments from TennCare based on false and fraudulent claims for at least 51 TennCare beneficiaries, and that it had an obligation to reimburse TennCare for overpayments.

85. Further, on or about September 28, 2017, representatives of the United States and the State of Tennessee made Walgreen aware, through its counsel, of overpayments for up to 14 additional TennCare beneficiaries.

86. More than four years have passed since Ms. Reilly's guilty plea for falsifying records and submitting false claims to TennCare for reimbursement, yet Defendant has made no attempt to refund the payments to TennCare as required by Section 10.14 of its Participating Pharmacy Agreement (Exhibit A, pg. 30).

87. For example, paragraph 10.14(C) of the Agreement requires Defendant to "comply with all federal and state requirements regarding fraud and abuse. . . ." In that respect, Section 1129J(d) of the federal Social Security Act mandates that a person who has received an overpayment must "return the overpayment to . . . the State" within 60 days.

88. The following chart summarizes, with respect to each patient (with names redacted), the record(s) that were altered as well as the amount wrongfully paid by TennCare due to such alterations.

TennCare Fraud Lab Report Comparison Chart n = no response indicated				Original Medical Lab Report		Altered Medical Lab Report		False Drug Lab	False Allergy	TennCare Payment	Adjusted TennCare Payment
No.	Date	Patient	Doctor / Nurse	Metavir	Fibrosis	Metavir	Fibrosis				
1.	10/6/14	REDACTED	REDACTED	F1	n	F3-F4	n			\$84,663	
2.	12/10/14	REDACTED	REDACTED	N	n	F3-F4	n	Yes		\$89,955	
3.	12/16/14	REDACTED	REDACTED	F0	0.12	F3-F4	0.72			\$169,326	
4.	12/16/14	REDACTED	REDACTED	F4	0.87	F4	0.87	Yes		\$181,422	
5.	1/5/15	REDACTED	REDACTED	F1-F2	0.39	F3-F4	0.74			\$60,490	
6.	1/8/15	REDACTED	REDACTED	F0	0.04	F3	0.58			\$60,474	
7.	1/29/15	REDACTED	REDACTED	F0	0.14	F3-F4	0.74			\$84,663	
8.	2/3/15	REDACTED	REDACTED	F0-F1	0.24	F3	0.59			\$56,442	
9.	2/6/15	REDACTED	REDACTED	F0	0.1	F3-F4	0.74			\$60,474	
10.	2/10/15	REDACTED	REDACTED	F1-F2	0.4	F3-F4	0.72			\$60,474	
11.	2/24/15	REDACTED	REDACTED	F0	0.06	F4	0.91			\$90,711	
12.	3/13/15	REDACTED	REDACTED	F2	0.57	F2	0.61			\$90,711	
13.	3/24/15	REDACTED	REDACTED	F0	0.14	F3	0.59			\$60,474	
14.	4/2/15	REDACTED	REDACTED	F0	0.14	n	0.59			\$60,474	
15.	4/6/15	REDACTED	REDACTED	F1-F2	0.38	n	0.67			\$79,977	
16.	4/21/15	REDACTED	REDACTED	F0	0.01	F3	0.72	Yes		\$84,672	\$84,663
17.	5/28/15	REDACTED	REDACTED	F3-F4	0.74	F3-F4	0.74	Yes		\$60,474	\$141,105
18.	6/1/15	REDACTED	REDACTED	n	n	n	0.72			\$30,237	
19.	6/10/15	REDACTED	REDACTED	F0-F1	0.25	F3	0.61			\$60,474	
20.	7/3/15	REDACTED	REDACTED	F1-F2	0.34	F3	0.66			\$169,326	
21.	7/7/15	REDACTED	REDACTED	F0	0.08	F3	0.59			\$60,474	
22.	7/21/15	REDACTED	REDACTED	F0	0.13	F3	0.72			\$79,986	
23.	7/24/15	REDACTED	REDACTED	F0	0.13	F3	0.61			\$79,986	
24.	7/28/15	REDACTED	REDACTED	F0	0.19	F3	0.59			\$60,474	
25.	8/7/15	REDACTED	REDACTED	F0	0.13	F3	0.59			\$79,977	
26.	8/20/15	REDACTED	REDACTED	F1-F2	0.42	F3	0.63			\$79,977	
27.	8/21/15	REDACTED	REDACTED	F0	0.2	F3	0.65	Yes		\$90,711	
28.	8/21/15	REDACTED	REDACTED	F4	0.85	F4	0.85	Yes		\$90,711	
29.	10/7/15	REDACTED	REDACTED	F0	0.15	F3	0.65			\$60,474	
30.	10/7/15	REDACTED	REDACTED	F3	0.59	F3	0.59	Yes		\$90,711	\$175,374
31.	10/10/15	REDACTED	REDACTED	F0	0.17	F3-F4	0.74	Yes		\$106,636	
32.	10/13/15	REDACTED	REDACTED	F2	0.55	F3	0.59			\$26,659	\$53,318
33.	10/19/15	REDACTED	REDACTED	F0	0.13	F3	0.61			\$145,134	
34.	11/9/15	REDACTED	REDACTED	F0	0.05	F3	0.72			\$60,474	
35.	11/17/15	REDACTED	REDACTED	F0	0.04	F3	0.64			\$90,720	
36.	11/18/15	REDACTED	REDACTED	F0-F1	0.23	F3	0.59			\$79,983	
37.	11/24/15	REDACTED	REDACTED	F0-F1	0.25	F3	0.65			\$60,474	
38.	12/10/15	REDACTED	REDACTED	F0	0.1	F3	0.59			\$60,480	
39.	12/21/15	REDACTED	REDACTED	F1-F2	0.36	F3	0.66			\$84,663	

40.	12/30/15	REDACTED	REDACTED	F1-F2	0.42	n	n	Yes		\$90,711	
41.	12/30/15	REDACTED	REDACTED	F0-F1	0.25	F4	0.78	Yes		\$84,663	
42.	1/14/16	REDACTED	REDACTED	F2	0.51	F3	0.59		Yes	\$90,711	
43.	1/29/16	REDACTED	REDACTED	F0	0.2	F3	0.63		Yes	\$60,480	
44.	2/16/16	REDACTED	REDACTED	F0	0.05	F3	0.65	Yes		\$84,663	\$84,672
45.	2/22/16	REDACTED	REDACTED	F0	0.16	F3	0.63		Yes	\$60,474	
46.	2/22/16	REDACTED	REDACTED	F0	n	F3	n			\$84,663	
47.	2/26/16	REDACTED	REDACTED	F0-F1	0.21	F3	0.61			\$84,663	
48.	3/4/16	REDACTED	REDACTED	F0	0.06	F3	0.66		Yes	\$145,152	
49.	3/15/16	REDACTED	REDACTED	F3-F4	0.73	F3-F4	0.73		Yes	\$120,948	\$181,422
50.	3/15/16	REDACTED	REDACTED	F2	0.51	F3	0.51		Yes	\$60,474	
51.	3/21/16	REDACTED	REDACTED	F0	0.21	F3	0.61			\$145,134	
52.	3/24/16	REDACTED	REDACTED	F0	0.06	F3	0.66			\$145,134	
53.	3/28/16	REDACTED	REDACTED	F1-F2	0.45	F3	0.72			\$60,474	
54.	3/29/16	REDACTED	REDACTED	F0	0.1	F3	0.6			\$60,480	
55.	3/29/16	REDACTED	REDACTED	F0	0.11	F3	0.61			\$145,134	
56.	3/31/16	REDACTED	REDACTED	F0-F1	n	F3	0.67			\$145,152	
57.	4/4/16	REDACTED	REDACTED	F0	n	F3	n			\$90,711	
58.	4/5/16	REDACTED	REDACTED	F0-F1	0.26	F3	0.66		Yes	\$90,711	
59.	4/5/16	REDACTED	REDACTED	F0-F1	0.26	F3	0.66			\$60,474	
60.	4/8/16	REDACTED	REDACTED	F2-F3	n	F3	0.69	Yes		\$79,977	
61.	4/8/16	REDACTED	REDACTED	F0-F1	n	F3	0.61			\$90,711	
62.	4/13/16	REDACTED	REDACTED	F0-F1	0.06	F3	n			\$145,134	
63.	4/14/16	REDACTED	REDACTED	F0	0.06	F3	0.66			\$145,134	
64.	4/27/16	REDACTED	REDACTED	F0	0.08	F3	0.61			\$60,474	
65.	4/27/16	REDACTED	REDACTED	F0	0.14	F3	0.64			\$60,474	
Total: \$5,677,527										<b>Total Adjusted:</b>	<b>\$5,929,954</b>

**Count I: False or Fraudulent Claims to TennCare in Violation of the FCA**

(31 U.S.C. § 3729(a)(1)(A))

89. The United States realleges and incorporates by reference paragraphs 1 through 88 as if fully set forth herein.

90. Beginning in October 2014 through December 2016, Defendant knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the TennCare program in violation of the FCA, 31 U.S.C. § 3729(a)(1)(A), specifically for claims for payment or approval of Hepatitis C prescriptions that it knew were not reimbursable.

91. Because of the Defendant's acts, the United States has suffered damages and is entitled to and requests treble damages under the FCA, in an amount to be determined at trial, plus a civil statutory penalty for each violation.

**Count II: False Records or Statements to TennCare in Violation of the FCA**

(31 U.S.C. § 3729(a)(1)(B))

92. The United States realleges and incorporates by reference paragraphs 1 through 88 as if fully set forth herein.

93. Beginning in October 2014 through December 2016, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of the FCA, 31 U.S.C. § 3729(a)(1)(B), including making false statements in prior authorization forms and medical records for TennCare enrollees with Hepatitis C, and using those false statements, forms, and records to obtain reimbursement from TennCare for pharmacy services that were not reimbursable.

94. Because of the Defendant's acts, the United States has suffered damages and is entitled to and requests treble damages under the FCA in an amount to be determined at trial, plus a civil statutory penalty for each violation.

**Count III: Knowing Retention of Overpayments in Violation of the FCA**

(31 U.S.C. § 3729(a)(1)(G))

95. The United States realleges and incorporates by reference paragraphs 1 through 88 as if fully set forth herein.

96. Defendant knowingly and improperly avoided an obligation to pay money to the Government, in violation of the FCA, 31 U.S.C. § 3729(a)(1)(G), when it learned of the overpayments made by TennCare for Hepatitis C prescriptions and failed to return the monies improperly paid for these false claims.

97. Because of the Defendant's acts, the United States has suffered damages and is entitled to and requests treble damages under the FCA in an amount to be determined at trial, plus a civil statutory penalty for each violation.

**Count IV: False or Fraudulent Claims to TennCare in Violation of the TMFCA**

(Tenn. Code Ann. § 71-5-182(a)(1)(A))

98. The State of Tennessee realleges and incorporates by reference paragraphs 1 through 88 as if set forth fully herein.

99. Beginning in October 2014 through December 2016, Defendant knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the TennCare program in violation of the TMFCA, Tenn. Code Ann. § 71-5-182(a)(1)(A), specifically for claims for payment or approval of Hepatitis C prescriptions that it knew were not reimbursable.

100. Because of the Defendant's acts, the State has suffered damages and is entitled to and requests treble damages under the TMFCA, in an amount to be determined at trial, plus a civil statutory penalty for each violation.

**Count V: False Statements to TennCare in Violation of the TMFCA**

(Tenn. Code Ann. § 71-5-182(a)(1)(B))

101. The State of Tennessee realleges and incorporates by reference paragraphs 1 through 88 as if set forth herein.

102. Beginning in 2014 through December 2016, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of the TMFCA, Tenn. Code Ann. § 71-5-182(a)(1)(B), including making false statements in prior authorization forms and medical records for TennCare enrollees with Hepatitis C, and using those false statements, forms, and records to obtain reimbursement from TennCare for pharmacy services that were not reimbursable.

103. Because of the Defendant's acts, the State has suffered damages and is entitled to and requests treble damages under the TMFCA, in an amount to be determined at trial, plus a civil statutory penalty for each violation.

**Count VI: Knowing Retention of an Overpayment in Violation of the TMFCA**

(Tenn. Code Ann. § 71-5-182(a)(1)(D))

104. The State of Tennessee realleges and incorporates by reference paragraphs 1 through 88 as if set forth herein.

105. Defendant knowingly and improperly avoided an obligation to pay money to the State, in violation of the TMFCA, Tenn. Code Ann. § 71-5-182(a)(1)(D) and in violation of its Participating Pharmacy Agreement, when it learned of the overpayments made by TennCare for Hepatitis C prescriptions and failed to return the monies improperly paid for these false claims.

106. Because of the Defendant's acts, the State has suffered damages and is entitled to and requests treble damages under the TMFCA, in an amount to be determined at trial, plus a civil statutory penalty for each violation.

**Count VII: Payment by Mistake of Fact**

107. Plaintiffs reallege and incorporate by reference paragraphs 1 through 88 as if fully set forth herein.

108. Defendant submitted, or caused the submission of, TennCare claims for pharmacy services for patients who did not meet the criteria for those pharmacy services, and such claims represent misrepresentations of material facts in that Defendant misrepresented the condition of the patient in order to claim that the services were reimbursable as billed.

109. Plaintiffs paid more money to Defendant than they would have based on the erroneous belief that Defendant was entitled to reimbursement and without knowing that

Defendant submitted, or caused to be submitted, requests for payment for pharmacy services that were not reimbursable.

110. Plaintiffs did in fact rely upon Defendant's fraudulent misrepresentations. As a result, from October 2014 through December 2016, Plaintiffs paid millions of dollars to Defendant.

### **Count VIII: Unjust Enrichment**

111. Plaintiffs reallege and incorporate by reference paragraphs 1 through 88 as if fully set forth herein.

112. Plaintiffs claim the recoveries of all TennCare monies by which Defendant has been unjustly enriched, including payments received by Defendant from billing for pharmacy services that were non-reimbursable based on the patients' condition at the time the services were provided.

113. By retaining monies received from TennCare pharmacy services and related services that were not reimbursable, Defendant retained money that was the property of TennCare and to which it was not entitled.

114. As a consequence of the acts set forth above, Defendant was unjustly enriched at the expense of Plaintiffs in an amount to be determined and which, under the circumstances, in equity and good conscience, should be returned to Plaintiffs.

### **Prayer for Relief**

The United States of America respectfully requests judgment be entered in its favor against Defendant as follows:

1. On Counts I, II, and III under the False Claims Act, judgment for the United States and against Defendant for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with costs of this action and all such further relief as may be just and proper.

2. On Count VII for payment by mistake, against Defendant for the amount it received from TennCare to which it was not entitled, plus interest, costs, and expenses.

3. On Count VIII for unjust enrichment against Defendant, for the damages sustained and/or amounts by which Defendant was unjustly enriched or amount by which Defendant retained money received from reimbursements paid by the United States to which it was not entitled, plus interest, costs, and expenses.

4. All other relief as may be required or authorized by law in the interests of justice.

The State of Tennessee respectfully requests judgment be entered in its favor against Defendant as follows:

5. On Counts IV, V, and VI under the Tennessee Medicaid False Claims Act, judgment for the State of Tennessee and against Defendant for the amount of the State's damages, trebled as required by law, and a civil penalty as required by Tenn. Code Ann. § 71-5-182(a)(1)(D) of not less than \$5,000 and not more than \$25,000 per claim, together with costs of this action and all such further relief as may be just and proper.

6. On Count VII for payment by mistake, against Defendant for the amount it received from TennCare to which it was not entitled, plus interest, costs, and expenses.

7. On Count VIII for unjust enrichment against Defendant for the damages sustained and/or amounts by which Defendant was unjustly enriched or amount by which Defendant retained money received from reimbursements paid by TennCare to which it was not entitled, plus interest, costs, and expenses.

8. All other relief as may be required or authorized by law in the interests of justice.

Respectfully submitted,

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By:



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/s/ Herbert H. Slatery III

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